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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MARVICH, MARIA	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,551	LAL ET AL.	
	Examiner	Art Unit	
	Maria B Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to an amendment filed 2/5/04. Claims 1, 3, 5, 6, 8, 9, 10, 12, 13, 17, 18, and 19 have been amended. Claims 20-21 have been added. Claims 1-21 are pending in this application.

Response to Amendment

Any rejection of Record in the previous action not addressed in this office action is withdrawn. There are new grounds of rejection herein that were not necessitated by applicant's amendment and therefore, this action is not final.

Claim Objections

Claim 6 is objected to because of the following informalities: in claim 6, line 1, the abbreviation "SIVcpz" is recited without defining it. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16, 18-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention. **This is a new rejection necessitated by amendment. This is a New Matter rejection**.

The limitation that "the oligonucleotides does not selectively hybridize to a region of the HXB2 strain between 4754-4984" has been added to claims 1, 6, 10 and 18. Applicant has not indicated where support for this limitation is found. The examiner has been unable to find literal support in the originally filed specification for the phrase "the oligonucleotides does not selectively hybridize to a region of the HXB2 strain between 4754-4984". Therefore, the limitation is impermissible NEW MATTER.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-21 are vague and indefinite in that the metes and bounds of "nucleotide positions". The claims recite a series of oligonucleotides that correspond to nucleotide positions of HIV-1 HXB2 and, therefore, a reference sequence is required to practice the claimed invention. However, there is no sequence listing or reference sequence provided in the specification or the claims for HIV-1 of the HXB2 strain in the specification. It is therefore unclear as to which possible HXB2 sequence is intended to be the reference sequence. However, applicants are cautioned that addition of a sequence listing to the specification may constitute New Matter. **This is a new rejection.**

Claims 1-21 are vague and indefinite in that the metes and bounds of " a region of the HXB2 between 4754-4984" are unclear. It is unclear if the oligonucleotides are excluded from binding to **any** nucleotide of this region or **all** of the nucleotides of this region. For example, does a primer that binds to nucleotides 4984-5000 bind to the region between 4754-4984? **This is a new rejection necessitated by applicant's amendment.**

Claims 1-4, 6-8, 10-12, 14, 18, 20-21 are vague and indefinite in that the metes and bounds of "selectively hybridizes" and "selective hybridization conditions" are unclear. The claimed conditions are ambiguous, as the specification does not teach conditions under which oligonucleotides selectively hybridize. Further, it is unclear what is considered "selective" hybridization. Therefore, the claimed nucleotide sequences are not defined. **This is a new rejection.**

Claim 20 recites the limitation "wherein amplification occurs" in claim 1. There is insufficient antecedent basis for this limitation in the claim. **This is a new rejection necessitated by applicant's amendment.**

Claim 21 recites the limitation "wherein amplification occurs" in claim 6. There is insufficient antecedent basis for this limitation in the claim. **This is a new rejection necessitated by applicant's amendment.**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. A nucleotide sequence of HIV-1 HXB2 is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The claims recite a series of oligonucleotides that correspond to nucleotide positions of HIV-1 HXB2. However, there is no sequence listing or reference sequence provided in the specification or the claims for HIV-1 of the HXB2 strain in the specification. It is therefore unclear as to which possible HXB2 sequence is intended to be the reference sequence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-7, 9, 10-11 and 13-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Pieniazek et al HIV Sequence Database (1998) p 1-6, applicant cited, see entire document. **This rejection is maintained for reasons of record in the office action filed**

10/2/03 and restated below. Furthermore, the rejection has been applied under 35 USC 102(a).

Pieniazek et al teach use of nested primers pairs GP40F1 and GP41R1 and GP46F2 and GP47R2 that correspond to SEQ ID NO: 1-4 (see e.g. page 2582, column 1, paragraph 5). These primers are used to detect HIV-1 subgroups by PCR amplification (see e.g. Figure 1).

Claims 1, 3-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Backus et al. EP 0 887 427 A2 (applicant cited), see entire document. **This rejection is maintained for reasons of record in the office action filed 10/2/03. The rejection is slightly altered below based upon applicant's amendment. Furthermore, the rejection has been applied under 35 USC 102(b).**

Backus et al teach methods and test kits for the detection of all known HIV-1 subtypes and/or HIV-2 subtypes (page 2, line 33-35). Backus et al teach primers designed to highly conserved regions of HIV-1 (see e.g. page 9, line 54-58) and ultimately to conserved regions of pol and env. Several probes between 18-40 nucleotides were designed (see e.g. page 5, line 6-41 and page 11, line 51-54). SEQ ID NO: 8 selectively hybridizes to nucleotides 4976-5004 of the HXB2 strain (see Blast 2 sequence results and e.g. page 9, line 25).

Claims 1, 3-4 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Backus et al. US 6,001,558, see entire document. **This rejection is maintained for reasons of record in the office action filed 10/2/03 and is restated below. The rejection is slightly altered below based upon applicant's amendment.**

Backus et al teach methods and test kits for the detection of all known HIV-1 subtypes and/or HIV-2 subtypes (abstract). Backus et al teach primers designed to highly conserved regions of HIV-1 (see e.g. column 10, line 50-65) that include pol and env (see e.g. column 3-5). Several probes between 18-40 nucleotides were also designed (see e.g. column 15). SEQ ID NO: 8 selectively hybridizes to nucleotides 4976-5004 of the HXB2 strain (see Blast 2 sequence results and e.g. page 9, line 25).

Response to Arguments

Applicants traverse the claim rejections under 35 U.S.C 102 as being anticipated by Pieniazek et al and Backus et al (EP 0 877 427 A2) on page 11-14 of the amendment filed 2/5/04. Applicants argue that Pieniazek et al and Backus et al are improper and therefore request withdrawal of the rejection. Pieniazek et al is improper as the document was published according to applicants in December 1998 and is 102(a) art and not 102(b) art as cited. Backus et al is improper as the international filing date is prior to November 29, 2000 and it therefore may not be relied upon as prior art.

Applicant's arguments filed 2/5/04 have been fully considered but they are not persuasive. The prior art date of Pieniazek et al was provided on the Form 1449 filed 10/02/03 as 1998. Upon clarification that the actual date of this reference is December 1998, the status of the rejection has been changed to 102(a). The instant invention is currently rejected under 35 USC 102(a) as being anticipated by Pieniazek et al and as such is proper. Upon reconsideration, the publication date, 12/30/1996, of Backus et al (EP 0 877 427 A2) has been applied to the

instant invention. Therefore, the instant invention is rejected under 35 USC 102(b) as anticipated by Backus et al and as such is proper.

Applicants traverse the claim rejections under 35 U.S.C. 102 (e) as being anticipated by Backus et al (6,001,558) on page 15 of the amendment filed 2/5/04. Applicants state that the claims have been amended to overcome the rejection by exclusion of primers that correspond to nucleotides 4754-4984 of HIV-1 HXB2 and by exclusion of SEQ ID NO: 9. The regions to which the SEQ ID NO: correspond are not taught in the specification however, applicants' state on page 18 of the amendment filed 2/5/04 that SEQ ID NO: 9 corresponds to nucleotides 4956-4984.

Applicant's arguments filed 2/5/04 have been fully considered but they are not persuasive. As determined by a Blast 2 sequence comparison between HIV-1 HXB2 gi8218025 and SEQ ID NO: 8, the primer taught by Backus et al corresponds to nucleotides 4976-5004. Therefore, this primer meets the limitations of the amended claims as it selectively hybridizes to a region between 4550 and 5126 but not to a region between 4754 and 4984. Moreover, applicants do not provide a reference sequence and therefore it is unclear to what the nucleotide numbering actually refers.

Applicants argue on pages 15-17 of the amendment filed 2/5/04 that the claim amendments do not constitute New Matter. Applicants reference MPEP 2173.05(i), which in summary states, "If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims." Applicants also recite *In re Johnson* and *In re Driscoll* as evidence that recitation of a genus minus two of the species need not be disclosed in the specification.

Applicants' arguments filed 2/5/04 have been fully considered but they are not persuasive. MPEP 2173.05(i) teaches that negative limitations can be used to define an invention given the negative limitations are found in the original disclosure. This particular reference is not specifically meant to teach that any negative limitation may be used in the claims only that once taught in the specification, a negative limitation may be relied upon to define the invention.

While applicants recite the teachings of *In re Johnson* and *In re Driscoll*, the particulars of these two cases are not equivalent to the instant case. In *in re Johnson*, which is simply summarized in *in re Driscoll,* the claims have been amended by the incorporation of negative limitations to avoid having the claim read on a lost interference count. However in this case, the specification discloses a broad genus that includes by example the two special classes excluded by the negative proviso. This is in contrast to *in re Welstead*, which most closely corresponds to the instant case. In *in re Welstead,* a new subgenus is introduced into the claims and this new subgenus is not described in the specification. As in the instant case, the introduction of a new subgenus that is not disclosed in the specification amounts to New Matter. Therefore, the rejection is maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

April 27, 2004.

GERRY LEFFERS
PRIMARY EXAMINER